

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-3, Part I
Chapter 16

May 16, 1994

1. Transmitted is a new chapter to Department of Veterans Affairs, Veterans Health Administration manual M-3, "Research and Development in Medicine," Part I, "General," Chapter 16, "Inventions and Patents."

2. The principal changes are:

a. Paragraph 16.01: Describes purpose and scope of chapter on inventions and patents (but not copywrites).

b. Paragraph 16.02: States VHA policy on the responsibility of VHA employee(s) to disclose inventions.

c. Paragraph 16.03: States authority which governs chapter.

d. Paragraph 16.04: Defines key terminology.

e. Paragraph 16.05: Defines medical center responsibility in disclosure of invention(s).

f. Paragraph 16.06: Defines VA Central Office responsibility for disclosure of inventions.

g. Paragraph 16.07: States requirements for acknowledgement of VA support.

3. Filing Instructions

Remove pages

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Insert pages

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16-1 through 16-3

16A-1 through 16A-2

4. RESCISSION: None.

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CHAPTER 16. INVENTIONS AND PATENTS

16.01 PURPOSE AND SCOPE

a. The purpose of this chapter is to communicate policies and procedures for reporting inventions by Veterans Health Administration (VHA) employees to the Office of the General Counsel (024), as required by 38 Code of Federal Regulations (CFR) 1.650 through 1.666. This chapter applies to all VHA employees whether or not their inventions result from funded research (Department of Veterans Affairs (VA) or extra-VA), or are even connected with VA employment. Disclosure of any invention, or believed invention, must be made regardless of where the ownership rights are believed to exist.

b. This chapter does not apply to:

(a) Inventions made under Cooperative Research and Development Agreements (see M-3, Pt. I, Ch. 13), or

(b) Materials to be copyrighted. NOTE: Under some circumstances computer software may be patented rather than copyrighted.

16.02 POLICY

a. VHA policy requires all employees to report their inventions to the Office of the General Counsel (024) for a determination of their ownership rights. Failure to report inventions may result in termination of research funding (if applicable), and/or other appropriate action.

b. This policy is intended to;

(1) Safeguard the respective rights of the United States Government and individuals covered by this chapter; and

(2) Encourage commercialization and technology transfer to the private sector.

c. VA will not assert title to inventions unconnected with VA employment and to which VA has made no contributions, but will issue a determination awarding all ownership rights to the inventor. The disclosure and subsequent determination of rights benefits the inventor by establishing clear title.

NOTE: Employees at field facilities report through their immediate supervisor and the facility director to the Office of General Counsel; facility directors report through the Regional Offices to the Office of General Counsel; VHA Central Office employees report through their Service Directors to the Associate Chief Medical Director to the Office of General Counsel.

16.03 AUTHORITY

The authority for this chapter may be found in:

a. Title 38 CFR 1.650 through 1.666; and

b. Title 37 CFR 501.

16.04 DEFINITIONS

For the purpose of this chapter, the following definitions apply:

a. Invention. The term "invention" includes any art, machine, manufacture, design, or composition of matter, or any new or useful improvement thereof, or any variety of plant which is or may be patentable or otherwise protectable under 35 United States Code (U.S.C.).

b. Employee. The term "employee" means any individual appointed or utilized in VA on a full-time, part-time, intermittent, consultant, attending, without compensation, or on-station fee basis, or in accordance with an on-station contract or on-station sharing agreement. All individuals are included except when special circumstances require the departure herefrom to meet the needs of VA. Such cases are to be approved by the Office of the General Counsel.

16.05 INVENTOR AND MEDICAL CENTER RESPONSIBILITIES

a. Inventor. The inventor must prepare an invention disclosure that provides the information specified in Appendix 16A. The disclosure should be read, signed, and dated by the inventor(s) and by the inventor's immediate supervisor to certify the accuracy of the statements.

b. Inventor's Immediate Supervisor. The inventor's immediate supervisor must promptly review the disclosure and indicate in a cover letter its accuracy. After reviewing this material, the supervisor must submit the total package to the facility Director.

c. Facility Director. The facility Director must submit the entire package with any comments and recommendations, including whether the invention is used, or is likely to be used in the public interest, and any such additional information as may be deemed helpful or necessary to the Office of the General Counsel (024).

16.06 VA CENTRAL OFFICE RESPONSIBILITIES

a. The General Counsel (024) reviews the invention disclosure and makes a determination of rights. NOTE: The criteria for the determination of rights in and to inventions are listed in 37 CFR 501.6. Determination may be one of the following:

(1) The United States (U.S.) Government shall obtain the entire domestic right, title, and interest in and to the invention. The Office of Research and Development will pay the cost of the patent application;

(2) The U.S. Government shall leave title to the invention with the employee subject to the reservation to the government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(3) The U.S. Government shall leave the entire domestic right, title, and interest in and to the invention with the employee.

(4) The U.S. Government shall transfer its interest in the invention to a university or other non-profit organization subject to the conditions set forth in 35 U.S.C. 202(e).

b. The Office of the General Counsel (024) shall promptly notify the inventor (employee) of its determination. Submissions involving inventions shall be made as promptly as possible in order to avoid delay which might jeopardize title to the invention or impair the rights of the inventor or the U.S. Government. No patent may be granted where the invention has been in public use or publicly disclosed for more than 1 year before the filing of a patent application.

c. Employee inventors may appeal a determination of rights by following the procedures described in 37 CFR 501.8. Special attention should be given to the time period within which an appeal may be filed.

16.07 ACKNOWLEDGEMENT OF FUNDING

An inventor or assignee must acknowledge sponsorship or funding by VA (and appropriate Research and Development Service) in all commercial literature, brochures and other promotional media.

REQUIRED CONTENT OF INVENTION DISCLOSURE

1. Nature of Invention. Describe the invention completely (sufficient to permit the preparation of a patent application), using the outline given below. Sketches, prints, photos, and any pertinent manuscript should be attached to this disclosure. Manuscripts generally following the outline are acceptable substitutes.

a. General purpose. State in general terms the purpose and object of the invention.

b. Background. Describe the prior art (identify by patent number or journal citation, if possible) and indicate how the invention differs and is more advantageous than prior art.

c. Technical description and operation. Describe completely the construction of the invention using reference characters to identify components in attached illustrations. Give a description of one complete operational cycle. If the invention relates to the synthesis or identification of a new composition of matter, describe the product in a structured form, if possible, and the process of making it. Include all available information regarding its physical characteristics and all test data evidencing its utility.

d. Nontechnical description. Describe on one page or less (double-spaced) the invention in terms understandable to non-scientists.

2. Circumstances Attending the Making of the Invention and Extent of the Government's Contribution to the Invention

a. Title of invention.

b. Department of Veterans Affairs (VA) project(s) number, or Public Health Service grant number under which it was developed (if applicable).

c. Full name of inventor(s), business address, telephone number (including area code), and grade and official title of position.

d. Indication of whether position is full or part-time (if part-time, number of eighths time).

e. Copy of position or functional description of inventor(s) at the time the invention occurred.

f. Name and address of the facility at which the invention was made.

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g. Contribution of VA of any of the following:

- (1) Facilities,
- (2) Equipment,
- (3) Materials or supplies,
- (4) Funds (dollar amount and source),

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- (5) Information,
- (6) Time or services on official duty, and
- (7) Time or services of other VA employees on official duty.

h. Contributions of any non-VA Federal Government entity of any of the following:

- (1) Facilities;
- (2) Equipment;
- (3) Materials or supplies;
- (4) Funds (dollar amount and source);
- (5) Information;
- (6) Time or services on official duty;
- (7) Time or services of other VA employees on official duty;

3. Whether invention was made entirely during working hours.

4. Whether the invention has previously been disclosed, as for example by an article submitted for publication, or in consultation with a manufacturer or attorney. If so, give details. In the case of an article, a copy should be attached, if possible, or the citation given.